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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,455	09/10/2003	Archibald I. J. Brain	108195.139/LMA-020	4910
23483	7590	03/23/2005	EXAMINER	
WILMER CUTLER PICKERING HALE AND DORR LLP 60 STATE STREET BOSTON, MA 02109			PATEL, MITAL B	
			ART UNIT	PAPER NUMBER

3743

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/659,455	Applicant(s) BRAIN, ARCHIBALD I. J. 60	
	Examiner Mital B. Patel	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-25 is/are allowed.
- 6) ☒ Claim(s) 26 and 27 is/are rejected.
- 7) ☒ Claim(s) 28-32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Callaghan et al (US 5,477,851).

3. **As to claim 26**, Callaghan et al teaches a laryngeal mask airway device **10**, comprising: an airway tube **14** having a proximal end and a distal end and defining a first passage; a mask portion **26** coupled to the distal end of the airway tube, the mask portion including an inflatable cuff, the cuff defining a central opening **27** at least when inflated, the mask portion being insertable through a mouth of a patient to an inserted location within the patient, the cuff surrounding a glottic opening of the patient when inflated and when the mask portion is at the inserted location, a sealed airway passage extending from the proximal end of the tube through the first passage to the glottic opening when the cuff is inflated and when the mask portion is at the inserted location, the proximal end of the airway tube being outside the patient's mouth when the cuff is at the inserted location, the cuff having a distal end, the distal end of the cuff being a part of the cuff that is furthest from the proximal end of the airway tube; one or more optical fibers **22** extending from a proximal end to a distal end and a lens (**although the lens is not shown, a fiber optic scope inherently has a lens**) connected to the distal end of

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the fibers, the lens being disposed near the cuff, the proximal end of the fibers being outside the patient's mouth when the cuff is at the inserted location, the fibers and lens providing a view of a region that extends from the lens through the central opening of the cuff, the lens being disposed such that a subsequently inserted endotracheal tube does not occlude a portion of the region, the portion of the region being between the endotracheal tube and the distal tip of the cuff (**See Col. 2, lines 34-40, which discloses that the optical fibers passes through the second branch 24, which the Examiner concludes would prevent an endotracheal tube from occluding the region between the tube and the distal tip of the cuff).**

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Callaghan et al (US 5,477,851).

7. **As to claim 27**, Callaghan et al teaches essentially all of the limitations except for wherein the airway tube is rigid. Rather Callaghan teaches a flexible tube.

However, one of ordinary skill in the art at the time of the invention would have expected Callaghan's tube to perform equally as well as Applicant's airway tube as the function of the tube to provide air to the patient is not altered by the rigidity of the tube.

Furthermore, Applicant has not disclosed how a rigid tube solves a stated problem, is advantages, or provides unexpected results.

Allowable Subject Matter

8. Claims 1-25 are allowed over the prior art of record.

9. Claims 28-32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

1. The following is a statement of reasons for the indication of allowable subject matter: As to claims 1, 11 and 28, the prior art of record does not teach nor render obvious the overall claimed combination of a laryngeal mask airway device having a mask portion that has an epiglottis elevator bar with the distal end of the bar defining an aperture with the bar positionable between a resting position and an open position including one or more optical fibers extending from a proximal end to distal end and a lens connected at the distal end of the fibers with the fibers extending through a first

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notch defined in an airway tube, the lens disposed near the aperture defined by the bar when the bar is in the resting position and the fiber and lens providing a view of a region that extends from the lens through the aperture. As to claims 4 and 18, the prior art of record does not teach nor render obvious the overall claimed combination of a laryngeal mask airway device having an airway tube defining a first notch extending along a length of the tube from a location on the tube towards the distal end of the tube, also having a mask portion with a backplate defining a ramp which defines a second notch and one or more optical fibers extending from a proximal end to a distal end and extending through the first notch and the second notch. As to claims 9 and 24 the prior art of record does not teach nor render obvious the overall claimed combination of a laryngeal mask airway device having an airway tube defining a first notch extending along a length of the tube from a location on the tube towards the distal end of the tube, also having a mask portion with a backplate defining a ramp which defines a second notch further including a collar disposed adjacent to the ramp with the collar defining an aperture and one or more optical fibers extending from a proximal end to a distal end and extending through the first notch, the second notch, and the aperture defined in the collar. It should be noted that the closest prior art is to Callaghan et al (US 5,477,854 and US Re.35,531) which teaches the use of a scooping instrument (optical fibers). However, Callaghan et al fails to specifically teach an apertured elevator bar through which the fibers/lens extend. Callaghan et al additionally fails to teach a second notch defined by a ramp in the backplate, and finally Callaghan et al fails to specifically teach not only the second notch defined by the ramp in the backplate but also fails to teach an

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apertured collar adjacent the ramp. There is no motivation in the prior art of record to modify the device of Callaghan to arrive at the claimed invention of claims 1, 4, 9, 11, 18, 24, and 28.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 571-272-4802. The examiner can normally be reached on Monday-Friday (11:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

 3/20/05
Mital B. Patel
Examiner
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